

Applicants: Arlindo L. Castelhana, et al.  
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**Remarks**

Claims 76-110 and 114-133 were pending in the subject application. By this amendment applicants have canceled claims 125 and 132, amended claims 76-99, 105, 110, 124 and 133 and added new claims 134-135. Accordingly, claims 76-110, 114-124, 126-131 and 133-135 are currently pending.

Support for amended claims 76 and 133 may be found inter alia in the specification as originally filed on page 69, line 26 to page 79, line 37, and on page 93, line 15 to page 94, line 12.

Support for new claims 134 and 135 may be found inter alia in the specification as originally filed on page 94, lines 3-12.

**Information Disclosure Statements**

On page 2 of the August 11, 2003 Office Action, the Examiner acknowledged receipt of the IDS filed on August 6, 2002 and on April 24, 2003. However, the Examiner noted that the IDS filed on February 12, 2002 and on March 22, 2002 were not included in the file. Accordingly, the Examiner requested that applicants resubmit the two IDS's again with all non-patent literature.

In response, applicants attach hereto a copy of the Form PTO-1449 submitted with applicants' February 12, 2002 IDS as **Exhibit A**. Applicants also attach hereto as **Exhibit B** a substitute Form PTO-1449 which differs from the Form PTO-1449 submitted with applicants' March 22, 2002 IDS in that the substitute Form PTO-1449 lists the U.S. Application Publication Nos. rather than the application nos. for the applications disclosed in applicants' March 22, 2002 IDS. Applicants also enclose copies of the non-patent references disclosed in the aforementioned Information Disclosure Statements. The numbering of the Exhibits corresponds

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to the numbering used in applicants' initial IDS submission. Applicants respectfully request that the Examiner initial the Form PTO-1449's and return a copy for applicants' files.

**Claim Objections - Claims 105 and 125-127**

On pages 2-3 of the August 11, 2003 Office Action, the Examiner objected to claims 105 and 125-127 as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. In particular, the Examiner alleged that Claim 105 is a product by process claim drawn to: "the prodrug of claim 103 wherein said prodrug is metabolized *in vivo* by esterase catalyzed hydrolysis" and that where a product is metabolized, or by what is metabolized, is of no patentable import to the product as claimed. The Examiner maintained that the product is treated on the merits of the product, not on processes associated with it.

In addition, the Examiner alleged that claim 125 is drawn to "the composition of claim 124 wherein said therapeutically effective amount is effective to treat a respiratory disorder or a gastrointestinal disorder" and that Claims 126 and 127 further limit composition to being effective for treating gastrointestinal disorders or respiratory disorders, respectively. The Examiner maintained that products are treated on the merits of the products, not on what the products are effective against.

In response, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution, applicants have canceled claim 125. Applicants have also amended claim 105 to recite "...wherein the prodrug is an ester of an alcohol or carboxylic acid group." Applicants contend

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that amended claim 105 now identifies the prodrug without reference to how the prodrug is metabolized. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this objection.

For the record, applicants point out that amended claim 124 includes within its scope pharmaceutical compositions comprising any amount of the compound of claim 76 or 99, and of a pharmaceutically acceptable carrier, whether for a respiratory disorder, a gastrointestinal disorder, or any other disorder.

**Claim Objections - Claims 77-99**

On page 3 of the August 11, 2003 Office Action, the Examiner objected to claims 77-99 because none of the claims end with a period.

In response, applicants have amended claims 77-99 and added a period at the end of each claim.

**Claim Objections - Claims 124 and 132**

On page 3 of the August 11, 2003 Office Action, the Examiner alleged that if claim 124 should be found allowable, claim 132 will be objected to under 37 C.F.R. §1.75 as being a substantial duplicate thereof. In addition, the Examiner alleged that the limitations of claim 132, which recites a packaged composition comprising the compound of claim 76 or 99, a container and directions, are of no patentable import to the composition as claimed.

In response, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution, applicants have canceled claim 132. Accordingly,

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this objection is moot. For the record, applicants point out that, as acknowledged by the Examiner, amended claim 124 includes within its scope packaged compositions as recited in canceled claim 132.

**Rejection under 35 U.S.C. §112, Second Paragraph - Claims 76-98 and 100-133**

On page 4 of the August 11, 2003 Office Action, the Examiner rejected claim 76 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner alleged that the phrase "wherein R<sub>5</sub> and R<sub>6</sub> are independently H, substituted or unsubstituted alkyl, or aryl" in claim 76 is indefinite because it is unclear if applicants intend the group to be: H; substituted or unsubstituted alkyl; or aryl; or if applicants intend the group to be: H; substituted or unsubstituted alkyl; or substituted or unsubstituted aryl. The Examiner also alleged that the claim is indefinite because it does not specify the identity of the moieties intended by the word "substituted."

In response, without conceding the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution, applicants have amended claim 76 to specifically recite the intended substituents at R<sub>5</sub> and R<sub>6</sub> without reciting the word "substituted." Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

**Rejection under 35 U.S.C. §112, Second Paragraph - Claim 110**

On page 4 of the August 11, 2003 Office Action, the Examiner rejected claim 110 under 35 U.S.C. §112, second paragraph, alleging that the phrase "...in a cell that is subject to abnormal

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stimulation of the A3 adenosine receptor..." is indefinite because it is unclear what is intended by "abnormal stimulation."

In response, without conceding the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution, applicants have deleted the phrase "that is subject to abnormal stimulation of the A3 adenosine receptor" from claim 110. Accordingly, the Examiner's rejection is now moot. For the record, applicants point out that amended claim 110 recites a method for inhibiting the activity of an A3 adenosine receptor in a cell that is, or is not, subjected to abnormal stimulation of the A3 adenosine receptor.

**Rejection under 35 U.S.C. §112, Second Paragraph - Claim 124**

On page 5 of the August 11, 2003 Office Action, the Examiner rejected claim 124 under 35 U.S.C. §112, second paragraph, alleging that the phrase "effective amount" is indefinite as the claim fails to state the function which renders an amount effective.

In response, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution, applicants have deleted the phrase "therapeutically effective amount" from claim 124. Accordingly, the Examiner's rejection is now moot. For the record, applicants point out that amended claim 124 covers any amount of the compound of claim 76 or 99, and of a pharmaceutically acceptable carrier.

**Rejection under 35 U.S.C. §112, Second Paragraph - Claims 77, 80 and 91-98**

On pages 5-6 of the August 11, 2003 Office Action, the Examiner

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rejected claims 77, 80 and 91-98 under 35 U.S.C. §112, second paragraph, alleging that claims 77, 80 and 91 lack antecedent basis because they contain moieties which do not appear in the Markush group of claim 76, and that the R5 and R6 groups in claims 91-98 lack antecedent basis in claim 76.

In response, without conceding the correctness of the Examiner's argument or relinquishing their right to pursue patent protection for any canceled subject matter but merely to advance prosecution, applicants have amended claim 76 to specifically recite the intended substituents. Applicants contend that claims 77, 80 and 91-98 now find antecedent basis in amended claim 76. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

**Rejection under 35 U.S.C. §112, Second Paragraph - Claim 133**

On page 6 of the August 11, 2003 Office Action, the Examiner rejected claim 133 under 35 U.S.C. §112, second paragraph, alleging that the phrase "treating the product of b) under suitable conditions to provide c)..." in claim 133 is indefinite for failing to define the method in a way which informs the public of the boundaries of the invention.

In response, applicants have amended claim 133 to recite "treating the product of step a) with acid in the presence of solvent..." and "treating the product of step b) with a chlorinating agent...". Applicants have also added new dependent claims 134 and 135 which specify particular reagents for use in the method of claim 133. Applicants contend that claim 133 as amended clearly recites applicants' invention. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

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**Rejection under 35 U.S.C. §102(a)- Claim 76**

On page 7 of the August 11, 2003 Office Action, the Examiner rejected claim 76 under 35 U.S.C. §102(a) alleging that the claim is anticipated by Campbell et al. In particular, The Examiner alleged that Campbell et al. discloses a compound on page 2414, bottom table and page 2415 which is identical to the compound of claim 76.

In response, applicants have amended claim 76 to specifically recite the intended substituents. In particular, applicants note that the compound disclosed in Campbell et al. is no longer encompassed by claim 76 because when R1 is 1-ethyl-imidazolidin-2-one, R5 must be phenyl. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

**Conclusion**

Applicants respectfully submit that the accompanying amendments and remarks serve to place all of the pending claims in condition for allowance.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

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No fee is deemed necessary in connection with the filing of this Amendment. However, if any fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

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